

§ 882.5830

21 CFR Ch. I (4–1–12 Edition)

an implanted cerebellar stimulator that was in commercial distribution before May 28, 1976 shall have an approved PMA or declared completed PDP in effect before beginning commercial distribution.

[44 FR 51730–51778, Sept. 4, 1979 and 49 FR 26574, June 28, 1984]

§ 882.5830 **Implanted diaphragmatic/phrenic nerve stimulator.**

(a) *Identification.* An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 7, 1986 for any implanted diaphragmatic/phrenic nerve stimulator that was in commercial distribution before May 28, 1976, or that has on or before July 7, 1986 been found to be substantially equivalent to an implanted diaphragmatic/phrenic nerve stimulator that was in commercial distribution before May 28, 1976. Any other implanted diaphragmatic/phrenic nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 51 FR 12101, Apr. 8, 1986]

§ 882.5840 **Implanted intracerebral/subcortical stimulator for pain relief.**

(a) *Identification.* An implanted intracerebral/subcortical stimulator

for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 1, 1989, for any implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976, or that has on or before March 1, 1989, been found to be substantially equivalent to an implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976. Any other implanted intracerebral/subcortical stimulator for pain relief shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 53 FR 48621, Dec. 1, 1988]

§ 882.5850 **Implanted spinal cord stimulator for bladder evacuation.**

(a) *Identification.* An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be

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filed with the Food and Drug Administration on or before December 26, 1996 for any implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976. Any other implanted spinal cord stimulator for bladder evacuation shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 882.5860 Implanted neuromuscular stimulator.

(a) *Identification.* An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976. Any other implanted neuromuscular stimulator shall have an approved PMA or declared completed

PDP in effect before being placed in commercial distribution.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 64 FR 18329, Apr. 14, 1999]

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) *Identification.* An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

§ 882.5880 Implanted spinal cord stimulator for pain relief.

(a) *Identification.* An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

§ 882.5900 Preformed craniostomosis strip.

(a) *Identification.* A preformed craniostomosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.